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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,283	03/03/2004	Birke Bartosch	P08199US00/BAS	9764
881	7590	10/12/2006		
STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			EXAMINER CHEN, STACY BROWN	
			ART UNIT 1648	PAPER NUMBER

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

10/791,283

Applicant(s)

BARTOSCH ET AL.

Examiner

Stacy B. Chen

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**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 22 September 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☒ The Notice of Appeal was filed on 22 September 2006. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: 1-4.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 5-8.  
Claim(s) withdrawn from consideration: 9-10.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

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Applicant's after-final amendment filed September 22, 2006 is acknowledged and entered. Claims 1-8 remain under examination. Claims 9 and 10 remain withdrawn from consideration because they are directed to non-elected subject matter.

***Claim Rejections - 35 USC § 103***

The rejection of claims 1-8 under 35 U.S.C. 103(a) as being unpatentable over Marasco *et al.* (WO 00/55335 A1, "Marasco") in view of Schlapp *et al.* (EP 1170367 A1, "Schlapp") and Lai *et al.* (*J. Virology*, 2000, 74(14):6339-6347, "Lai"), is withdrawn with respect to claims 1-4, and maintained with respect to claims 5-8.

The claims are drawn to a method for producing pestivirus-like particles *ex vivo* comprising the steps of:

- Providing a first nucleic acid sequence comprising a packaging competent retroviral-derived genome;
- Providing a second nucleic acid sequence comprising a cDNA encoding core proteins from said retrovirus;
- Providing a third nucleic acid sequence comprising a cDNA encoding a polyprotein comprising successively a pestivirus core protein, and a E<sup>ms</sup> protein and/or pestivirus E1 protein and/or a pestivirus E2 protein, and optionally a pestivirus p7 protein;
- Transfecting host cells with said nucleic acid sequences and maintaining the transfected cells in culture for sufficient time to allow expression of the cDNAs to produce structural proteins from pestivirus and retrovirus; and

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- Allowing the structural proteins to form virus-like particles which do not include the pestivirus core protein.

Specifically, the core proteins are from a retrovirus selected from the group consisting of MLV, ALV, RSV, MPMV, HIV-1, HIV-2, SIV, ELAV, CAEV and HFV. The E<sup>ms</sup>, E1 and E2 pestivirus proteins, and optionally p7 pestivirus protein are from the same pestivirus. The pestivirus is BCDV, SFV or BDV. Also claimed are the virus particles produced from the methods.

Marasco teaches pseudotyped lentiviral vectors comprising:

- A first vector containing a lentiviral gag gene (core)
- A second vector containing an env gene (gp41/120)
- A lentiviral pol gene (reverse transcriptase) encoding a lentiviral pol protein on the first or second vectors, and
- A packaging vector containing a nucleic acid sequence encoding a desired molecule.

The env gene can be heterologous to the lentiviral pol protein, selected from a variety of viral sources, including pestiviruses among others (Marasco, claims 1-3). Lentiviruses include FIV, ELAV and HIV, for example (Marasco, claims 7-17). Marasco is silent on the use of pestivirus core and E<sup>ms</sup> protein. (Note that the instant claims do not require E1, E2 or p7.) However, Schlapp teaches BVDV virus-like particles comprising a BHV-1 genome backbone with BVDV (a pestivirus) proteins including N (core protein packages viral RNA to form the nucleocapsid, N protein), E<sup>ms</sup>, E1 and E2 (Schlapp, page 3, lines 9-25).

The rejection is withdrawn with respect to claims 1-4 in view of Applicant's persuasive arguments. Namely, there is no motivation in the cited references to incorporate the core gene

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and the E<sup>ms</sup> s gene from pestivirus into Marasco's construct. While Schlapp teaches pestivirus-like particles that have the core gene and the E<sup>ms</sup> gene, there is no motivation to include the core gene in the Marasco construct.

However, with respect to claims 5-8 which are drawn to pestivirus-like particles having retroviral core particles and a pestivirus E<sup>ms</sup> protein, Marasco provides the motivation to incorporate the E<sup>ms</sup> protein taught by Schlapp. It would have been obvious to use the pestivirus E<sup>ms</sup> gene as the env gene of Marasco's construct. One would have been motivated to use E<sup>ms</sup> of Schlapp because Marasco teaches that pestivirus env proteins are useful in the invention (Marasco, page 6, second full paragraph, and claim 3). The E<sup>ms</sup> protein is part of the envelope that is antigenic, thus functioning in the same manner as Marasco's suggested pestivirus envelope protein (pseudo particle). Therefore, the product claims remain rejected.

### ***Conclusion***

Claims 1-4 are allowable. Claims 5-8 are rejected. Claims 9 and 10 are withdrawn from consideration.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

*Stacy B. Chen* 10/5/06  
STACY B. CHEN  
PRIMARY EXAMINER